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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,739	04/09/2001	Avi J. Ashkenazi	P1468R1D1	1184
9157	7590	10/13/2004	EXAMINER	
GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			SAUNDERS, DAVID A	
			ART UNIT	PAPER NUMBER

1644

DATE MAILED: 10/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

828,739

Applicant(s)

ASHKENAZI et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 10/27/03
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 3-16, 18-21 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 3-16, 18-21 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/27/03 (as an IDS) has been entered.

Regarding the Lynch reference submitted in the IDS of 10/27/03, the examiner notes that this reference post-dates applicant's effective filing date. The examiner finds no claims of Lynch that would conflict with the claims of the instant application.

The examiner notes that no amendment or urgings were filed following the final rejection mailed 7/18/03; however, the examiner has withdrawn the 112, 6th paragraph rejection of record.

Claims 1, 3-16 and 18-21 are pending and under examination.

The following new ground of rejection is stated under 35 USC 112, second paragraph.

Claims 1, 3-16 and 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 the term "specifically cross-reacts" has unclear metes and bounds, because it is not clear what percentage of binding strength defines a cross-reactive degree of binding (e.g. when binding to a second antigen read as compared to binding to a first antigen).

It appears that the instant specification (pages 21-22) provides a precise definition of "specifically cross-reacts" in terms of a percentage reflecting the extent of binding, where in the percentage is 50-100%.

Applicant's disclosure, however, is not this simplistic. If one looks at Table 2 (page 66) then one notes that antibodies 3H1.18.10 and 3H3.14.5 show cross reactivities with DR4, DcR1 and DcR2 indicated, in all cases as "+/-". The legend under this table defines "+/-" as indicating "25-49% binding." This is below the limit of 50% set forth at pages 21-22, yet applicant considers the 3H1.18.10 and 3H3.14.5 antibodies as within the scope of claim 1; otherwise, how can applicant recite these in dependent claims 12-14?

The following rejections of record in papers 4 and 7, are repeated and maintained, in the absence of any amendment or arguments following the final rejection of paper 7.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's claims may all be considered as analogous to single means claims. As such, these claim fail to comply with the enablement requirement of 112, first paragraph. In re Hyatt 218 USPQ 195. See citation thereof in Fiers v. Sugano at page 1606.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant failed to possess the claimed DNA, vector, host cells and methods of use thereof.

Applicant's specification has merely shown possession of three hybridoma cell lines that secrete monoclonal antibodies in accord with the nature of the disclosed antibodies. However, with respect to nucleic acids (DNA), applicant has merely reviewed several art known methods of providing such DNA, such as obtaining the encoding DNA from hybridoma cell lines, from phage display libraries, etc. Such methods, however, do not provide a description of its structure (sequence). Specification containing statement that claimed DNA sequence is part of invention and reference to potential method for isolating sequence does not satisfy written description requirement of 35 U.S.C. 112, since specification does not describe DNA itself. *Fiers v. Sugano* 25 USPQ2d 1601.

The decision of *In re Hyatt* is cited to indicate that the claims are not enabled under the 112, first paragraph rejection stated by the examiner in paper 4. The same paragraph of *Fiers v. Sugano* (page 1606) also indicates that such claims fail to meet the description requirement.

As to applicant's urgings that applicant has "demonstrated a reduction to practice of the recited antibodies and DNA encoding such antibodies" (paper 6, page 5), the

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examiner concurs that the antibodies have been reduced to practice. However the DNA, which is claimed, has not been reduced to practice. Where is any DNA sequence encoding the antibodies disclosed? As set forth in *Fiers v. Sugano*, mere teachings of methods of how to isolate and sequence the encoding DNA do not provide for possession/description. Applicant's urgings have failed to address why the rationale set forth in *Fiers v. Sugano* regarding lack of enablement and lack of description under, 112, first para. is in error.

Applicant's urgings filed 4/10/03 have been considered but are unconvincing of patentability.

The following 102 rejections of record (paper 40) are maintained.

Claims 1-12 and 15-21 are rejected under 35 U.S.C. 102(e) or (g) as being entirely anticipated by Ashkenazi (6,342, 369).

Ashkenazi is a proper reference under 102 (e), since it is to "another" and was filed on May 14, 1998, prior to June 12, 1998 date which applicant claims benefit of in the instant application.

Ashkenazi discloses an antibody (3F11.39.7), which binds to Apo-2 and cross-reacts with DR4. See col. 48, lines 46-62. This antibody blocks apoptosis and also has agonistic activity (col. 31, lines 41-48 and col. 48, lines 36-45).

As to the instant claims to DNA sequences encoding the antibody, vectors and host cells and use thereof, as well as to various types of antibody constructs (e.g. humanized), and conjugates of such antibodies, all of these aspects are taught by Ashkenazi. See especially col. 31, line 5-col. 37, line 8.

Claim 12 is included because the 3F11.39.7 antibody of Ashkenazi has the binding characteristics of the three recited antibodies, in accord with applicant's definition of "cross-reactivity" (para. spanning pp. 21-22) and Table 2.

Claims 1-12 and 15-21 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. As noted supra, Ashkenazi (6, 342, 369) has invented the same subject matter.

Applicant has urged (in paper 6) that the instant specification (pages 21-22) provides a precise definition of "specifically cross-reacts", presumably in terms of a percentage reflecting the extent of binding, and that the teaching of Ashkenazi does not show that the 3F11.39.7 antibody has this extent of cross-reactive binding. The examiner considers that the extent of cross-reactive binding may be estimated from the OD readings shown in Fig. 11; in the absence of precise figures, the examiner estimates this extent to be about 25%. Thus a simplistic reading of claim 1, in light of the specification at pages 21-22 would exclude the 3F11.39.7 antibody of Ashkenazi et al.

Applicant's disclosure, however, is not this simplistic. If one looks at Table 2 (page 66) then one notes that antibodies 3H1.18.10 and 3H3.14.5 show cross reactivities with DR4, DcR1 and DcR2 indicated, in all cases as "+/-". The legend under this table defines "+/-" as indicating "25-49% binding". This is below the limit of 50% set forth at pages 21-22, yet applicant considers the 3H1.18.10 and 3H3.14.5 antibodies as within the scope of claim 1; otherwise, how can applicant recite these in dependent claims 12-14? Also, if applicant wants to include antibodies having a "+/-" reactivity of

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25-49% in Table 2, then the examiner should certainly include the 3F11.39.7 antibody of Ashkenazi as within the scope of claim 1 and as "having the biological characteristics" of the antibodies recited in claim 12.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Monday-Thursday from 8:00a.m to 5:30p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/tgd

September 23, 2004

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
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